Disrupting the Industry: G-CON's Impact on Cell and Gene Therapy Manufacturing

Dennis Powers
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Introduction

In this Q and A, Dennis Powers, G-CON's Senior Vice President of Product and Strategy, answers questions about the POD's effect on therapeutics with off-site manufacturing of modular/podular cleanrooms and G-CON's overall impact on the cell and gene therapy sector for manufacturing advanced therapies in prefabricated cleanrooms.

Q: What is happening in the industry right now in cell and gene therapy?

It's a very exciting time in our industry right now, especially with everything that's been happening in the cell and gene therapy space. We saw back in 2017 after 20 plus years of the industry investing in the research and development of advanced therapeutic medicines, the industry finally reached a critical inflection point when the first CAR-T therapies were approved by the FDA for commercialization. It was in that year that both Novartis' KYMRIAH® and Kite-Gilead's YESCARTA™ autologous therapies were approved by the FDA, which was great news. That same year, Spark Therapeutics' LUXTURNA™ gene therapy for a rare retinal genetic disorder which causes blindness, was also approved. Early in 2019, we saw that AveXis-Novartis' gene therapy product for spinal muscular atrophy, which is a horrific genetic disease in infants, was approved by the FDA. So, from what we're seeing right now in the industry, this is just the beginning. The FDA recently stated that they expect new drug applications to hit 200 per year by the end of 2020 and by the year 2025, they expect that the number of approved cell and gene therapies is going to be in the 10 to 20 per year range, so this is a tremendous increase which is going to happen very quickly. It's really just the tip of the iceberg for a lot of these companies with these therapies because they treat a life threatening condition and fill an unmet medical need; therefore they're getting fast-track designation from the FDA with an expedited approval process, which means they can get their critical therapies to the market much faster than historic timelines.

Do you feel the industry is being disrupted? Is that a true statement to make?

Yes, I would definitely agree. I mean, this is the next wave in the industry. Cell and gene therapy is the next biotech. We saw this with monoclonal antibodies 20-25 years ago, so yes, the cell and gene therapy space is definitely disrupting the industry and it's causing manufacturers, CMOs and suppliers to all think differently about how drug products are manufactured and distributed to patient populations around the world.

What are some of the primary drivers pushing the facility needs in the cell and gene therapy space?

When we talk about the drivers of what's pushing the industry and what's important to the manufacturers, one of the first things we need to look at is what trends are we seeing in the industry right now? Certainly, there's been a big trend toward consolidation within the industry where we're seeing some of the larger pharma companies go out and acquire the smaller cell and gene therapy companies that have a targeted pipeline. In the past two years, we've seen Kite get acquired by Gilead, AveXis get acquired by Novartis, Juno was acquired by Celgene, which has now been acquired by Bristol-Myers Squibb, so it's something we're seeing a lot of, even on the CMO front where companies like Brammer and Paragon, which specialized in the cell and gene therapy space, be acquired by Thermo Fisher and Catalent, respectively. This is being largely driven by the competition for the existing capacity and expertise within the industry. As we said, this is disrupting the industry. These are new technologies which require a new manufacturing model and it really is driving competition for that existing capacity. This is especially true for viral vectors, which are a critical component for both the cell and gene therapies. The vectors are either a critical raw material used in the cell therapy process or it's actually the product itself, depending on the type of therapy, and with the number of products there are right now in late phase clinical trials which are approaching commercialization, the demand for viral vectors has really outgrown the supply, and this has led to a capacity crunch and a push to build out new manufacturing capacity both by drug manufacturers and the CMOs. This is one of the biggest needs we're seeing right now and there is a similar situation brewing with some of the other raw materials like plasmids, which are critical to manufacturing.

Based on the above, would you say the "rules" are changing?

Certainly. These new demands and new manufacturing modalities are changing. We're seeing demands from both a process and facility design standpoint. When we look at the fact that there's so few commercially approved products currently available, there's a limited expertise out there in the industry, so it certainly is having an impact and we certainly see that the potential for companies that have a new therapeutic that is going to address an unmet medical need, timing is absolutely critical for these companies to get their product to market as fast as possible. There's a patient population who desperately needs these therapies. It's very important that these companies are able to get manufacturing capability and capacity much faster than we've seen in our industry historically.

Do you think that is a primary need?

Absolutely. When you look at the fact that a lot of these drugs are getting accelerated approvals from the FDA, these manufacturers have to ensure that they have a pathway for establishing their manufacturing capability that's aligned with their pathway for regulatory approval, which means, in many cases, they need to have a new facility or capability established and validated within 18 months. In some cases they want to do it in 12 months or less, so to be able to design, build and validate in that timeframe, you really need a new, innovative way of executing projects, designing and building facilities to get those clients there so they have their capacity – they have their capability to the drug to those patients.

Q: How has G-CON had an impact on the issues, trends and challenges faced in this area?

When we look at G-CON's history, the company and the cleanroom PODs were actually born from the personalized cancer vaccine industry over 10 years ago, so developing these new innovative cleanroom technologies that meet the needs of cell and gene therapy has really been in our DNA from the very beginning. We've essentially grown our business and advanced the design of our PODs by working closely with our clients, including drug manufacturers, CMOs, equipment suppliers and engineering partners, to understand these new requirements as they've been evolving. G-CON has been able to leverage that knowledge and expertise from these relationships from the projects that we've worked on to establish and design new POD platforms for different manufacturing modalities like CAR-T, gene therapies, viral vectors, etc. This standardized approaching using pre-designed platforms allow our clients to realize the design and construction of new facilities much faster.

Q: Walk us through a process with G-CON when a client requests PODs or a facility platform design for an advanced therapy project?

It covers a pretty broad range. We have a client base that includes small start up companies all the way up to large global companies just getting into the cell and gene therapy space for the first time. The starting point is always trying to understand: What are their process requirements? How are we designing the PODs around their process? How does the facility need to be designed from a cGMP standpoint? What are their capacity requirements? Are we designing and building for clinical manufacturing vs. commercial? Does the client need a facility that will address their short term needs for clinical manufacturing, but ultimately be used for commercial as well? A lot of the clients that we work with need to have a new infrastructure that is designed with the inherent flexibility that's going to allow them to adapt as the market need changes or as their manufacturing network needs change as these new technologies and these new therapies get more optimized as new process technologies come online. We have to really try to understand what their short-term needs are, what their long-term needs are and putting together a POD facility design that's going to meet all those needs.

Q: We know there are many options out there. Why is G-CON seeing more clients and companies in the industry make a shift towards PODs?

G-CON is at a point now where we've established ourselves as leaders in the industry for prefabricated autonomous cleanrooms. We've executed projects across a broad range of applications, not just in cell and gene therapy, but in aseptic fill/finish, biologics manufacturing and oral solid dosage and we've executed those projects for 5 of the top 10 global pharma companies to date, so I think we are now at a point where the technology in the PODs have been validated by the industry, we're a known entity and we have a very consistent track record of executing projects on time, on budget and helping our clients more rapidly deploy their manufacturing capabilities successfully.

Do you think the industry sees that G-CON is meeting their needs?

Absolutely. I think in every project we deliver for a client, there's tremendous value and certainly for the projects that we've done in the cell and gene therapy space. We have clients that are coming back to us saying, "Because of the POD approach to our new facility, we've been able to manufacture and deliver more product to our patients much faster than was ever possible in the past." We have clients who are able to get their first therapies or their first product out of a POD based facility in 12 to 14 months from the very start of a project, which is tremendous. Historically, that would be 18 to 24 months, at best, so we've cut that timeline in half. When we talk about getting critical therapies to the patients who need them, it's a very rewarding experience to work with these clients and manufacturers who are producing these therapies. At the very end, what matters most is getting these drugs out to market quickly for the patient. To be able to achieve and be part of that is a huge honor. It's very rewarding. It's why we do what we do.

About the Author:

Dennis Powers is the Sr. Vice President Product and Strategy for G-CON and has over 25 years of experience working in the biopharmaceutical industry on both the manufacturing and supplier sides of the business. He has held positions in various technical and management functions including engineering, operations, project management, and validation. Through his career, Dennis has worked closely with numerous companies in the biopharmaceutical industry to provide process, equipment, and facility solutions to meet their specific needs. He is an active member of ISPE and PDA.

Dennis received his B.S. in Mechanical Engineering at the University of Delaware and his M.S. in Management from NYU Polytechnic University.

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